

APR 7 2006

510k Premarket Notification

SECTION 3
K060366
510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

The applicant is: Advanced Medical Optics, Inc
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92799-5162, USA

The contact person is: Toni Elliott
Regulatory Affairs Professional
Tel: (614) 834-1204
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Date the Summary was prepared: February 8, 2006

Device that is the subject of this notification:

Trade/Proprietary Name: The AMO Ophthalmic Surgical System
Classification Name: Phacofragmentation System

The devices to which substantial equivalence is claimed:

510(k) Number	Clearance Date	Device
K003638	02/13/2001	Mojave Cataract Extraction System (Marketed as the Sovereign Compact Cataract Extraction System)
K911808	06/25/1991	Gemini Ophthalmic Surgery System (Marketed as the Series 20000 Legacy and Accurus Ophthalmic Systems)
K961310	06/27/96	Premiere II Microsurgical System (Marketed as the Millennium Microsurgical System)

DEVICE DESCRIPTION

The AMO Ophthalmic Surgical System is a device designed for use in performing anterior segment ophthalmic surgery (cataract) and posterior segment ophthalmic surgery. The device is intended for use in performing phacoemulsification, phacofragmentation, diathermy, irrigation/aspiration, vitrectomy, extrusion and silicone oil injection and extraction. The materials, basic scientific concepts, physical properties and intended use of the AMO Ophthalmic Surgical System are substantially equivalent to those of the

Mojave Cataract Extraction System, the Accurus Ophthalmic Surgical System and the Millennium Microsurgical System.

INDICATIONS FOR USE

The AMO Ophthalmic Surgical System is a modular ophthalmic microsurgical system that facilitates both anterior segment (i.e., cataract) and posterior segment (i.e., vitreoretinal) ophthalmic surgery. The posterior segment surgery module is optional. The modular design allows the users to configure the system to meet their surgical requirements.

TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE

Anterior Segment Surgery Modes

For **anterior segment surgical procedures**, the System provides the following main modes: diathermy, phacoemulsification, irrigation/aspiration and vitrectomy.

- The **Diathermy** (bipolar) mode is used to coagulate blood vessels during a surgical procedure and, in some cases, to coapt the conjunctiva following a procedure.
- The **Phacoemulsification** mode is used to break up the nucleus of a cataractous lens, allowing it to be aspirated from the eye through a small incision.
- The **Irrigation/Aspiration** mode allows for controlled aspiration of cortical material from the eye, while maintaining intraocular stability by replacing aspirated material with the irrigation solution. Irrigation can be gravity-fed or pressurized. Pressurized irrigation is only available if the posterior segment module is installed.
- The **Vitrectomy** mode is used to cut and remove vitreous from the anterior segment of the eye during secondary intraocular lens implantation, following vitreous loss associated with trauma or during primary cataract surgery.

These anterior segment surgery modes are substantially equivalent to the anterior segment surgery modes of the predicate devices.

Posterior Segment Surgery Modes

- For **posterior segment surgical procedures**, the System provides the following main modes: vitrectomy, extrusion, silicone oil injection and extraction, linear diathermy and phacofragmentation.
- The **Vitrectomy** mode provides vitreous cutting in the posterior segment using a vitrectomy cutter. This enables the surgeon to remove the vitreous for treatment of various posterior segment conditions.
- The **Extrusion** mode acts similarly to the Irrigation/Aspiration mode for anterior segment surgery. It provides vacuum and irrigation for removing ocular material

from the eye while maintaining intraocular stability during posterior segment surgical procedures. Irrigation can be gravity-fed or pressurized.

- The **Linear Diathermy** (bipolar) mode provides diathermy (cautery) power proportional to foot pedal activation.
- The **Silicone Oil** mode is used to infuse silicone oil into (and remove it from) the posterior segment of the eye to replace fluid lost during vitreoretinal surgical procedures.
- The **Phacofragmentation** mode delivers ultrasonic power for the fragmentation of the crystalline lens through a *pars plana* incision in the posterior segment thereby allowing the material to be more easily aspirated from the eye.

These modes are substantially equivalent to the posterior segment modes of the Accurus and the Millennium.

SUMMARY OF NON-CLINICAL TESTS

Prior to commercialization, safety tests of the AMO Ophthalmic Surgical System will demonstrate compliance with applicable requirements of the following standards:

Standard / Guideline	Title
Can/CSA C22.2 No. 601.1-M90	Medical Electrical Equipment – Part 1: General Requirement for Safety
EN60601-1	General requirements for safety. Collateral standard. Safety requirements for medical electrical systems. Section 1.1 Collateral standard: Safety requirements for medical electrical systems
EN60601-1-1	Medical electrical equipment. General requirements for safety. Collateral standard. Safety requirements for medical electrical systems. Section 1.1 Collateral standard: Safety requirements for medical electrical systems
EN60601-1-2	Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility. Requirements and tests
EN60601-1-4	Medical electrical equipment. General requirements for safety. Collateral standard. General requirements for programmable electrical medical systems
EN60601-2-2	Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of high frequency surgical equipment. Part 2-2: Particular requirements for the safety of high frequency surgical equipment
EN61000-4-2	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrostatic discharge immunity test. Basic EMC publication

Standard / Guideline	Title
EN61000-4-3	Electromagnetic compatibility (EMC). Testing and measurement techniques. Radiated, radio-frequency, electromagnetic field immunity test
EN61000-4-4	Electromagnetic compatibility (EMC). Testing and measurement techniques. Electrical fast transient/burst immunity test
EN61000-4-5	Electromagnetic compatibility (EMC). Testing and measurement techniques. Surge immunity test
ISO 10993-1	Biological evaluation of medical devices-Part 1: Evaluation and testing
UL60601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety
ISO 11135	Advancement of Medical Instrumentation Recommended Practice Guideline "Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
ISO 11137	Sterilization of Health Care Product Requirements for Validation and Routine Control – Radiation Sterilization

All materials coming into contact with the patient or the patient fluid path have been cleared in previous 510(k)s, with the exception of two new materials. A biocompatibility assessment of the two new materials was conducted. The new materials found in one of the disposable modular tubing packs were tested using the tests listed in the table below.

TEST	RESULT
Medium Eluate Method (MEM) - GLP	Non-cytotoxic
Agar Overlay – Solid Sample – GLP	Non-cytotoxic
Agar Overlay – Normal Saline Extract - GLP	Non-cytotoxic

SUMMARY

The technological characteristics affecting the performance of the System are substantially equivalent to those of the predicate devices previously listed. The AMO Ophthalmic Surgical System will be manufactured in compliance with FDA and ISO quality system requirements. System validation and verification will demonstrate that the functional requirements and system specifications have been met prior to commercial release.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Medical Optics, Inc.
c/o Toni D. Elliott
Regulatory Affairs Professional
1700 East St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92799

Re: K060366

Trade/Device Name: The AMO Ophthalmic Surgical System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: February 8, 2006
Received: February 13, 2006

Dear Ms. Elliott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman MD", with a long horizontal flourish extending to the right.

Malvina B. Eydelman, M.D.
Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 2
INDICATIONS FOR USE

510(k) Number (if known): Unknown at this time

Device Name: The AMO Ophthalmic Surgical System

Indications for Use:

The AMO Ophthalmic Surgical System is a modular ophthalmic microsurgical system that facilitates both anterior segment (i.e., cataract) and posterior segment (i.e., vitreoretinal) ophthalmic surgery. The posterior segment surgery module is optional. The modular design allows the users to configure the system to meet their surgical requirements.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Dennis L. Mc Carthy
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

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